



TO: All-Faculty, All-Administrators, Research Staff

FROM: Dr. Danielle D. Gagne, Chairperson, Human Subjects Research Committee (HSRC)

RE: AU Policy on Research Involving Human Subjects

DATE: Fall 2022

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I. INTRODUCTION

Individuals wishing to conduct research at Alfred University (AU) involving human subjects must conform to applicable federal, state, and local laws and regulations. To oversee and regulate research involving human subjects most effectively, AU maintains a standing committee known as the Human Subjects Research Committee (HSRC) under Federal IRB 00007472. It is the purpose of this committee to review research protocols involving human subjects and evaluate risks to subjects, protection against risks, and potential benefits likely to result from proposed research. Guidelines are provided by the Federal Policy for the Protection of Human Subjects (the Common Rule) and by Federal Regulation 45 CFR (Code of Federal Regulation) Part 46, as published in the Federal Register (<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html>)

Research is hereby defined as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition may be funded or unfunded, or may be conducted as a component of another program not usually considered research. For example, demonstration and service programs may include evaluation components that constitute research activities under this definition.

In addition, *student research* (i.e., projects conducted by student investigators who gather data about living individuals outside the class) that involves obtaining data in a systematic investigation about living individuals through intervention or interaction with those individuals, or through the collection of their identifiable private information, may be subject to review by the HSRC, even if the activities are not designed to develop or contribute to generalizable knowledge.

The attached policy statement is to remind all faculty, administrators and staff researchers that:

- we have an ethical and legal obligation to protect the interests of human research subjects to the fullest extent possible;
- all supervisors of student research are expected to instruct their students in elements of sound research design, which includes understanding and protecting rights of human subjects; and
- **all physiological and behavioral research involving human subjects must be reviewed** by the HSRC and must comply with informed consent requirements.

II. COMMITTEE MEMBERSHIP

The committee is charged with the mission to ensure that all research done under the auspices of Alfred University conforms to state and federal regulations governing health, privacy and safety of human subjects in research. The HSRC comprises at least five full-time faculty members from different academic departments whose research or teaching is affected by these regulations. Efforts are made to ensure that the membership is not composed of entirely men or entirely of women, and that the committee include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. Additionally, the HSRC committee includes at least one member who is not otherwise affiliated with the University.

Current members of the HSRC:

Danielle Gagne, Chair, CLAS (Psychology, Gerontology, & Communication Studies; 2023)
Melissa Dudley, School of Graduate and Continuing Studies (2024)
John D'Angelo, CLAS (Chemistry; 2024)
Emrys Westacott, CLAS (Philosophy; 2024)
Elizabeth Matson, CLAS (Mathematics & Computer Science; 2024)
Shelly Freyn, College of Business (Marketing; 2025)
Mark Whitman, External Reviewer (Social and Behavioral Sciences, Alfred State College)

Please direct any questions or comments to any committee member, who will then forward your concerns to the committee Chair. Please note that all policy decisions involving research with human subjects are rendered by the entire committee, not by any individual member. The Chair of the committee will convene meetings on an as-needed basis.

III. HUMAN SUBJECTS RESEARCH POLICY at ALFRED UNIVERSITY

The HSRC reviews all research conducted by faculty, staff, and/or students involving human subjects for the protection of the rights, welfare, and well-being of the subjects, and the rights of the researcher and of the University. Guidelines for these decisions have been provided by the Federal Policy for the Protection of Human Subjects (the Common Rule) and by Federal Regulation 45 CFR (Code of Federal Regulation) Part 46 (cf. 34 CFR Part 97), “Protection of Human Subjects in Research,” published in the Federal Register, and applicable ethical standards as published by professional groups and societies.

Many Alfred University scholars conduct research involving human subjects using in-depth interviews, survey research, direct observation of behavior, and physical experimentation. All Alfred University researchers have a moral and legal responsibility to protect the interests of human research subjects to the fullest extent possible, in accordance with professional standards of ethical conduct.

Investigators will need to submit a proposal for review if it meets any one of the following criteria:

- The activity is considered *research*, defined as a systematic investigation designed to develop or contribute to generalizable knowledge.
- The research involves obtaining information about living individuals.
- The research involves interaction or intervention with the individuals.
- The information collected can be used to identify individuals (i.e., the identity of the subject is or may be readily ascertained by the investigator associated with the information)
- The activity involves members of a vulnerable or protected category (e.g., children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons).

In general, adequate protection of human research subjects requires that the committee considers the following when reviewing proposals:

- Assessment of Anticipated Benefits.** Research may directly or indirectly benefit individual persons or society. The HSRC will look for a clear statement of benefits to subjects, as well as identification of the knowledge researchers expect to gain.
- Risks are identified and assessed.** Risks to subjects can be physical, psychological, social, and/or economic. Risks should be reasonable in relation to the anticipated benefits to the subjects or to the importance of knowledge that may reasonably be expected to result.
- Risks should be minimized.** Precautions, safeguards, and alternatives should be incorporated into the research design to reduce the probability of harm. Risk and discomfort to subjects should be minimized whenever possible.
- Risks are Reasonable in Relation to Anticipated Benefits.** The HSRC will evaluate the risk/benefit ratio, taking into account research design and methodology, subject population (e.g., children, pregnant women, terminally ill), and timeline. In research where no direct benefits to the subject are anticipated, the HSRC will evaluate whether the risks presented by procedures performed solely to obtain generalizable knowledge are ethically acceptable.

- **Informed consent is adequate.** Informed consent should be sought from each prospective subject or the subject's legally authorized representative. Subject(s) should be fully informed for what purposes data will be used, procedures, potential risks, and benefits. Informed consent should be written in clear language.
- **Provisions for privacy and confidentiality are clearly described.**
 - *Privacy* can be defined in terms of having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. The HSRC will review provisions to protect the privacy of subjects to prevent or mitigate non-intentional identification.
 - *Confidentiality* pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission. This includes safeguards used to maintain the confidentiality of physical and digital data, such as use of codes and encryption, using firewall and password-protected computers and programs, locked filing cabinets and offices, etc.
- **Subjects are selected and treated ethically.** The HSRC will evaluate whether the selection of subjects is equitable, remuneration or compensation is non-coercive, the special needs of vulnerable populations are addressed, and that penalties are not assessed for withdrawal of participation.

University policy requires that *all* proposals, grants, and behavioral research projects involving human subjects be submitted to the Human Subjects Research Committee (HSRC) for its written approval *prior to data collection*.

A. STUDENT RESEARCH

In all cases, course instructors are expected to instruct their students in elements of sound research design which includes understanding and protecting the rights of human subjects.

Classroom Instruction

The instructor assumes all risk and culpability for research activities conducted in the classroom.

Students conducting research involving human subjects as a normal class requirement in which the data will be used *for classroom purposes only* are not directly subject to HSRC procedures. Note that this data cannot be used beyond the classroom.

Research Projects and Theses

Students conducting major research projects (e.g., Independent study, field research, capstone projects, honors projects or theses, undergraduate and graduate theses) are considered principal investigators with a faculty sponsor and *are expected* to comply with all HSRC procedures.

For undergraduate student research, faculty advisors must submit all materials in email to the HSRC and copy the student researcher(s). Proposals should be complete and free of grammatical and typographical errors. Incomplete proposals will be returned without review for corrections.

B. ETHICS TRAINING

As of September 1, 2015, all individuals listed as the Principal Investigator (PI) or who are listed as a faculty sponsor on a submitted proposal must complete a free, on-line training module in Human Subjects Research, which is available through the Collaborative Institutional Training Initiative (CITI).

Instructions:

- Go to <https://about.citiprogram.org/>
- Create a Username and Password
- Add an affiliation: Alfred University
- Modules:
 - Faculty, staff, and students conducting social, behavioral, or educational research with human subjects must select the course labeled *Social and Behavioral Responsible Conduct of Research* (9 modules)
 - You must score at least 80% on the assessment portion to “pass” and receive your certificate. Upon completion, researchers should print and/or save a certificate of completion, which must be sent to the HSRC with the proposal.
 - NOTE: Completion of a different training module does not satisfy this requirement.

In order to remain in compliance with the Ethics Training requirement, researchers, including faculty/staff sponsors ***must retake the training modules every three years.***

Proof of completion (i.e., certificate of completion) should be emailed to the HSRC chair with the proposal.

Additional instructions can be found on the CITI website:

<https://www.citiprogram.org/citidocuments/citiinstructions.htm?>

IV. REVIEW PROCESS

In order to conduct research with human subjects, all researchers must submit a Human Subjects Review (HSRC) application, which includes:

- a) a completed proposal cover sheet;
- b) complete proposal;
- c) evidence of human subject research ethics training;
- d) Informed consent form;
- e) a copy of all research instruments.

The researcher must submit the application and related material to the chair of the Human Subjects Review Committee. Allow at least two weeks for review during the academic terms. Review may take longer during certain times of the year, such as Summer term, Allen term, or during finals weeks.

Levels of Review

All proposals for research with human subjects are submitted to the HSRC for review. Proposals will fall under one of three categories: Exempt, Expedited, or Full review. Principle Investigators can request or suggest a review level; ***The HSRC determines the level of review.***

Regardless of the level of review (Exempt, Expedited, or Full), researchers should expect that review of HSRC proposals will take at least 2 weeks (or longer if submitted during “off” times, such as Allen Term or Summer recess). This does not account for any revisions required to the proposal. ***Please plan accordingly.***

1. Exempt Review.

One experienced member of the HSRC conducts Exempt reviews. If the HSRC believes that the proposed research is not suitable for Exempt Review, it will be subjected to Expedited or Full Review, as appropriate.

Proposals suitable for Exempt Review must involve no greater than minimal risk and fall into one of the categories below:

- Research involves only the collection or study of existing data, documents, and/or records;
- research in established or commonly accepted educational settings (including, not limited to schools and colleges);
- research on normal education practices (e.g., research on regular and special education instructional techniques, research on effectiveness of or the comparison among instruction techniques, curricula, or classroom management methods);
- research using educational tests (cognitive, diagnostic, aptitude and achievement) if information is recorded so that subjects cannot be identified; or
- research involving interview procedures or direct observation of public behavior except where any of the following conditions exist:
 - data are recorded so that subjects can be identified;
 - data, if subjects become known outside of the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject’s financial standing or employability; or
 - research that deals with sensitive aspects of the subject’s own behavior, such as illegal conduct, drug use, sexual behavior, or the use of alcohol.

2. Expedited Review

The Expedited Review is conducted by a subset of the HSRC which involves the Chair and two other committee members.

Proposals suitable for Exempt Review must involve no greater than minimal risk and fall into one of the categories below:

- research previously reviewed and approved by the HSRC
- reviews with minor changes in approved changes with one year of original approval
- identification of subjects will not put them at risk for criminal or civil liability, or be socially or economically damaging

Federal guidelines stipulate that research qualifying for Expedited Review *cannot* include protected classes or vulnerable populations, such as children, pregnant women, prisoners, and individuals with disabilities, or individuals with mental illness.

3. Full Review

Any research not qualifying for Exempt Review or Expedited Review is subject to Full Review by the HSRC. If desired the researcher and sponsor (if applicable) is welcome to attend the HSRC review meeting and provide justification as to why they feel the proposal should be approved.

The outcomes of Exempt and Expedited Reviews will be provided to researchers via email. If revisions are required, they will be detailed in this communication. If Full Review is needed, the HSRC Chair will contact the researcher and sponsor (if appropriate) to determine whether an in-person meeting is needed or desired.

Researchers cannot begin to collect data until HSRC approval is granted. Unless otherwise noted, approvals will be valid for one year, after which researchers must contact the HSRC to request a renewal of the initial approval. Depending on the review level of the initial proposal, re-review may be necessary.

V. NON-COMPLIANCE

All Alfred University researchers must comply with HSRC policies.

Failure to comply with HSRC policy may constitute a serious legal and/or ethical breach and therefore, must be reported to the HSRC immediately if discovered. Examples of noncompliance include, but are not limited to:

- Failure to conform to approved research protocol(s)
- Disclosure of participants' information to unauthorized parties
- Changing research protocols without HSRC approval
- Conducting research before formal approval is given (or without seeking approval at all) or after approval has expired
- Failure to provide accurate and truthful information to the HSRC or participants

If noncompliance with HSRC standards is suspected, please contact the HSRC chair directly at hsrc@alfred.edu. If upon consultation with HSRC members and/or the Provost's office it is determined that researchers have not complied with HSRC policies, researchers must cease all research activity immediately. Written notification of the order to cease research will also be provided to the researchers' division head, dean, and/or faculty members, as deemed appropriate.

VI. PROPOSAL REQUIREMENTS

Your proposal must include all of the sections.

A. Cover Sheet (see end of packet)

B. Proof of Completion of CITI Ethics Training

C. Major purpose/Background

This section must provide sufficient non-technical background so that the committee can understand the motivation for the proposed research, the benefits and risks associated with the proposed research, and how the results of the research will be used. Citation of relevant scholarly literature and research question(s) or hypothesis (ses) under investigation are expected.

D. Subjects and procedures

Describe the research procedures, participant recruitment procedures, and any possible remuneration/compensation. Identify the targeted participants with respect to age, gender, and other defining characteristics.

E. Safeguards for subjects

Describe any potential negative consequences incurred through participation (or, state that minimal risk is expected). Indicate how risk or negative consequences will be minimized for participants.

Be sure to include the contact information for the principal investigator, faculty sponsor (if applicable), and chair of the HSRC.

F. Time frame

Provide the time frame for the participation of the subject, and the overall timeline for completion of the project.

G. Care and use of results

Indicate steps taken to ensure *confidentiality* (e.g., Password-protected and/or encrypted computer files, locked filing cabinets, locked offices, non-identifying participant key codes, etc.)

Describe how the *results of the research will be used* (e.g., presentation at conferences, publication, etc.) and how the data will be *maintained and destroyed* (if applicable).

H. Appendices

You must include all the items that will be provided to subjects, including:

1. Informed consent form (see Informed Consent checklist and sample)
2. Debriefing statement
3. Any other instruments in their entirety (e.g., questionnaires, forms, Likert Scales, etc)

INFORMED CONSENT CHECKLIST

- *Describe the research broadly*, offering the subject or the representative sufficient opportunity to consider whether the subject should or should not participate.
- *Explain the purposes of the research*, including the anticipated benefits to subjects or the importance of knowledge that may reasonably be expected to result;
- *Identify any potential risks or discomforts* to subjects and their relation to the anticipated benefits or the importance of knowledge that may reasonably be expected to result;
- *Describe the expected scope and duration of the subject's participation*, including the procedures to be followed, and identify any procedures which are experimental.
- *Describe the extent to which confidentiality* of records identifying the subject will be maintained and how data will be destroyed.
- Explain whether any compensation and medical and/or mental health treatments are available in the event of injury or emotional distress.
- State that participation is;
 - voluntary,
 - that refusal to participate will involve no penalty or loss of benefits, and
 - the subject may discontinue participation at any time without penalty.
- Explain whom to contact (provide mailing address, e-mail, and phone number) for answers to pertinent questions about the research and research subject's rights.
 - Student Researcher (if applicable)
 - Principal investigator/Faculty
 - Chair, Human Subjects Research Committee
 - AU Wellness Center (if applicable)
- Do not include exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or appears to release the research investigator, the sponsor, the institution or its agents from liability for negligence.
- Use error-free and grammatically correct language that is understandable to the subject and/or or the representative.

Sample Consent Form

Survey of Undergraduate Students

You are invited to be in a research study of characteristics of undergraduate students enrolled in introductory anthropology classes. You were selected as a possible participant because you are 18 years of age or older and enrolled in an anthropology class at Alfred University. We ask that you read this form before agreeing to be in this study.

This study is being conducted by Alfred Alfredson, Ph.D., and Jane Student., Alfred University, Alfred, NY 14802.

Background Information

The current study will investigate attitudes and behaviors associated with anthropology.

Procedures

If you agree to participate in this study, we ask that you fill out the following questionnaires in full and be forthright in your answers. On the pages that follow, you will find surveys of attitudes and behavior patterns, as well as a demographics questionnaire. Completion of this study is estimated to take approximately 15-20 minutes.

Risks and Benefits of Being in the Study

While unlikely, it is possible that you may feel discomfort while considering some of the survey items that deal with potentially troubling situations. You are free to discontinue your participation at any time during the study simply by exiting the survey. In the unlikely event that this survey causes mild distress, the researchers suggest that you consult with the Alfred University Wellness Center (607-871-2300) or another mental health service provider in your immediate vicinity. Participation in this study may provide you with some additional knowledge about research related to anthropology and your participation will hopefully add to this knowledge base.

Confidentiality

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a participant. Research records will be kept in a locked file; only the researcher will have access to the records. Records will be kept for at least three years after completion of the study, after which records may be destroyed at the discretion of the researcher.

Voluntary Nature of the Study

Your decision whether or not to participate will not affect your current or future relations with Alfred University. If you decide to participate you are free to withdraw at any time without penalty.

Contacts and Questions

The researcher conducting this study is Alfred Alfredson. If you have questions about your participation in this study that you would like to ask before participating, please exit this survey and contact the researcher electronically at alfredson@alfred.edu. If you have any questions now, or later, related to the integrity of the research, (the rights of research subjects or research-related injuries, where applicable), you are encouraged to contact Dr. Danielle Gagne, Chair of the Alfred University Human Subjects Research Committee, at (607) 871-2213 or electronically at HSRC@alfred.edu.

Statement of Consent

I have read the above information. I consent to participate in the study.

Signature

Date

Printed Name

HUMAN SUBJECT RESEARCH COMMITTEE -- PROPOSAL COVER SHEET

Project Title	_____	
Project Status	<input type="checkbox"/> New Research <input type="checkbox"/> Modification to existing research <input type="checkbox"/> Extension request for existing research (no changes)	
School/College	<input type="checkbox"/> College of Business <input type="checkbox"/> School of Art & Design <input type="checkbox"/> NYS College of Ceramics	<input type="checkbox"/> School of Graduate & Continuing Studies <input type="checkbox"/> Inamori School of Engineering <input type="checkbox"/> College of Liberal Arts & Sciences
Purpose of Research	<input type="checkbox"/> Institutional (Student Affairs, CDC, etc.) <input type="checkbox"/> Faculty Research <input type="checkbox"/> Dissertation Research <input type="checkbox"/> Master's Research	<input type="checkbox"/> Independent Study (graduate) <input type="checkbox"/> Independent Study (undergraduate) <input type="checkbox"/> University Honors <input type="checkbox"/> Class project
Type of Research	<input type="checkbox"/> Archival <input type="checkbox"/> Experiment <input type="checkbox"/> Survey <input type="checkbox"/> Hybrid <input type="checkbox"/> Other (describe _____)	
Subject Population	<input type="checkbox"/> Children and/or Adolescents (aged 0-18) <input type="checkbox"/> Other vulnerable (e.g., prisoners, individuals with disabilities, etc.) <input type="checkbox"/> Adults (aged 18+)	
<p>Is this research in collaboration with another academic Institution? <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Is this research in collaboration with an outside agency, company, or other? <input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>If "yes," name: _____</p>		
Principle Investigator:	_____	
	Name, dept	
Local Contact Information:	Address: _____	
	e-mail: _____	
Faculty Sponsor (if student PI)	_____	
	Name, dept	
Local Contact Information:	Address: _____	
	e-mail: _____	